

Plants with Novel Traits Working Group - Summary Report



October 27, 2008 - Ottawa, Ontario

The National Forum on Seed's (NFS) Working Group on Plants with Novel Traits (PNTs) held its third meeting in Ottawa on October 27, 2008. Approximately 50 plant breeders, seed growers, seed distributors, crop producers, representatives of industry associations and government officials attended the meeting.

The objective of the Working Group on PNTs is to ensure regulations do not constitute an unnecessary barrier to innovation and commercialization for products derived through conventional plant breeding. The Advancing Canadian Agriculture & Agri-food program (ACAAF) under the auspices of Agriculture and Agri-food Canada (AAFC) in part funds NFS activities, including ongoing work on PNT and novelty.

The purpose of the one-day meeting was to solicit feedback on the Canadian Food Inspection Agency's (CFIA) draft Directive, entitled "Plants Regulated Under Part V of the Seeds Regulations". Specifically, the meeting objectives were to identify areas that need clarification and identify remaining outstanding questions. Further objectives were to highlight new policies as well as changes to current policies, and to identify the path forward.

Context

Presentation: Dale Adolphe, NFS

Mr. Adolphe briefly reviewed the path of the Working Group on PNTs. Out of the first meeting in Ottawa March 6, 2006 came a series of recommendations to government including:

- greater transparency in the regulatory system;
- the concept of a single window for assessing novelty;
- the use of experience from other countries;
- tiered risk assessment; and,
- post-approval monitoring.

A response to these recommendations from CFIA's Plant Biotechnology Office (PBO) and Animal Feed Division, which incorporated Health Canada (HC) input was received by the NFS in July 2006. The response outlined 10 proposed activities to address the recommendations:

1. Clarify newness & environmental linkages
2. More clearly define and interpret novelty trigger

3. CFIA draft guidance document on novelty
4. Recognizing early consultation as due diligence
5. Exploring concept of single window approach
6. Recognition of other countries' data
7. Development of an appeal mechanism
8. Recognizing scientific rationale in lieu of de novo data
9. Clarifying no split decision policy
10. Commitment to working with stakeholders

Mr. Adolphe noted that there has been progress in most of the areas. The draft guidance document on PNTs, which was the focus of this meeting, is a key component in making progress on many of the items.

During a brief discussion following Mr. Adolphe's presentation, it was noted that the draft Directive under discussion is a general directive, and will include annexes to provide further guidance in determining whether a new trait has the potential to affect the environmental safety or end use of example crops. The annex provided at this time is for agricultural field crops. Appendices for other crops, such as turf grasses and fruit or nut trees, still need to be developed.

Presentation: Dr. Stephen Yarrow, CFIA

Dr. Yarrow further framed the day's discussion with a brief overview of CFIA activities on clarifying for plant breeders and importers what is considered as a novel trait in a plant and the purpose of the draft Directive. Plant breeders and importers have voiced their concerns regarding determining whether or not their new plant lines contain a novel trait. The directive aims to clarify which plants are subject to regulation under Part V of the Seeds Regulations. Other goals of the Directive are to provide greater clarity and predictability for developers of new plants; to formalize policies that have been until now provided verbally from the PBO; and to address concerns, where possible, from stakeholders, including those raised at previous NFS meetings.

The new Directive does not affect regulation of novel foods or feeds. The scope of the directive is limited to the regulation of the environmental release of PNTs, defined as plants expressing traits that are both new **and** could affect a plant's environmental safety..

Dr. Yarrow underlined that the directive should satisfy traditional plant breeders that the environmental release of the vast majority of their plant lines will not trigger regulation under Part V. Over the last 20 years, almost all confined research field trials have been for plants developed with recombinant DNA (rDNA) techniques or mutagenesis.

This meeting is one of the key next steps in soliciting feedback on the draft directive. A CFIA-led e-mail consultation also is in the works.

Discussion

There was some discussion around the Canadian approach to seed regulation, which is product-based. It is the presence of a novel trait in a plant, regardless of how the trait has been introduced, that triggers regulation (i.e. just because a trait has been produced through genetic engineering does not automatically mean it is regulated under Part V of the *Seed Regulations*). This is a fundamental difference from the European Union (EU) approach, which is process-based. In their system, every event resulting from rDNA is regulated. Dr. Yarrow pointed out that while there are differing views in Canada about these approaches, many in the EU are beginning to question their process-based approach.

The view was broadly expressed that the draft directive is an important step in the right direction, and there is a strong desire to keep the momentum going. The lack of predictability until now has created a climate of uncertainty that is preventing innovation, particularly among conventional plant breeders. It was noted that another important stakeholder is the authorized Canadian distributor who wishes to import product.

Dr. Yarrow was asked about the status of the single window proposal, to which he replied that greater clarity is needed around the definition. Rollout is probably about a year away, he said.

In response to another question, Dr. Yarrow confirmed that appendixes to the draft directive for other crops will be developed.

Focus on Proposed Guidelines

Most of the day was devoted to detailed discussion around the key elements of the draft guidance document. For each chapter in the document, a CFIA representative presented an overview. This was followed each time by small round-table discussions where participants identified questions and concerns, which they then reported back in plenary sessions.

Presentation: Tanya Fielding, CFIA

Ms. Fielding set out the scope of the draft Directive. Its purpose is to provide breeders, developers and importers of new plants with guidance when determining whether their plant is regulated under Part V of the *Seeds Regulations*.

Section 2 of the Directive deals with determining whether a plant is a PNT, i.e. expresses a trait or traits that are both new and could affect a plant's environmental safety. Appendix 1B provides examples of the types of considerations breeders should take into account. Section 3 lays out the notification and information requirements for environmental releases of PNTs. Section 4 details the notification and information requirements for environmental releases of plants other than PNTs. Section 5 deals with the authorization for environmental release of PNTs and other plants regulated under Part V.

Ms. Fielding presented the definition of a novel trait under the *Seeds Regulations*, and underlined that the method used to introduce the trait is not a factor in determining whether or not a trait is novel. PNTs are plants into which one or more traits have been introduced intentionally, and where the trait is both new to cultivated populations of the species in Canada and has a potential to affect the specific use and safety of the plant with respect to the environment and human health. A key principle is that it is the responsibility of proponents to consider whether their product has a novel trait and to self-identify to the CFIA. That said, the CFIA has the right at any time to require a proponent to provide scientific justification for the determination that a plant is not a PNT.

Ms. Fielding explained certain breeding objectives that are likely to trigger regulation, and outlined the two criteria for determining if a trait may trigger assessment as a potential Novel Trait:

- Newness of the trait to distinct stable populations in the Canadian environment, **and**,

Plants with Novel Traits

Working Group - Summary Report



October 27, 2008 - Ottawa, Ontario

- Potential to affect the use and environmental safety of the plant

Ms. Fielding described the process for proponents wishing to seek guidance. She then reviewed Appendix 1B, which is intended to provide further guidance on the types of considerations plant breeders should take into account when determining if a new trait has the potential to affect the environmental safety and specific end use of a plant. Several types of traits are discussed in this appendix, such as compositional changes, morphological changes, changes in biotic or abiotic stress tolerances, male sterility and fertility restoration, and yield increase.

Discussion

Major themes in the discussion were: the need for further clarity on determining if a trait has a potential to affect environmental safety and examples (similar to the current appendix), the issue of risk versus potential for the industry, resource implications for public sector plant breeders, and international trade considerations.

A general sentiment was that while the draft Directive makes progress in clarifying what is a plant with a novel trait, there is still a need for further clarity. More examples in the document would be helpful. For instance, could CFIA work through practical examples of plant breeders who would have done a self-evaluation to determine whether their plant has a novel trait? Also helpful would be examples where morphological changes did result in significant environmental impacts. Dr. Yarrow indicated that more examples along these lines can be developed for the appendixes and that the draft Directive needs to be more specific about when the PBO should be approached.

The view was widely expressed that more clarity is needed on how risk versus potential will be evaluated. The comment was made that the document describes how to avoid risk but does not address how to promote innovation.

The comment was made that the draft Directive casts such a wide net that it could be interpreted as catching almost every new development as "new". This could present major resource challenges, particularly for public sector plant breeders. The question was also posed as to how the regulations will impact on public breeding programs for low value crops such as feed barley or small acreage crops like pulses. For example,

introducing into barley rust resistant trait(s) from barley germplasm imported from Egypt could result in the introduction of a novel trait. Another example could be increasing rust resistance by 20% through conventional breeding using an existing Canadian barley variety – would such a trait now be considered novel? If the plant has the potential to infect wild grasses, could that trigger novelty? Public breeders do not have the resources for research and documentation collection for a crop where there is no guarantee of long-term return from seed sales.

While self-identification may be the right way to go, concern was expressed about a scenario where the proponent determines a trait is not novel, and then CFIA comes back later with a different determination. Part of this concern could stem from the qualifying language used throughout the draft Directive. Ultimately, the concerns are twofold: business risk and liability, and the potential barrier to bringing innovation to the Canadian agriculture industry.

From a trade perspective, a question was raised as to how product versus process would be reconciled? If a product triggers regulation in another country where the trigger is process-based, does that mean the proponent in Canada has to submit to the regulatory process even though it has been approved under a product-based process? In other words, does someone have to notify the CFIA of the release of a product in the Canadian environment if it has been authorized for environmental release in another country? CFIA responded yes; safety determinations and decisions to authorize are done independently of those done in other countries. In term of environmental release, the behavior or impact of a plant can vary considerably given the climate and local biodiversity. Therefore, a plant cultivated in Australia may not behave in the same way as it would in Canada.

Other questions/comments:

- If a trait in a species is authorized for unconfined release, does that mean under PNT guidelines it is no longer novel? (Dr. Yarrow responded that this was correct). Therefore, does that also apply to approved rDNA submissions where the trait has been approved for unconfined release?
- How broad is the definition of "change in management practice" in the draft document?

- Who will decide what constitutes “significant change”?
- Dr. Yarrow indicated that CFIA needs to further define the term “widely cultivated prior to 1996.”

Presentation: Tanya Fielding, CFIA

Turning to Section 3, Ms. Fielding set out the notification and information requirements for environmental releases of PNTs. The three types of releases are:

- Confined release for research purposes
- Unconfined environmental release
- Commercial confined environmental release (a new form of release still under development)

She then outlined the types of information which can be used to demonstrate the environmental safety of a PNT, including experimental data, scientific rationale and peer-reviewed literature.

Discussion

The overall theme of this discussion was about how to define and measure risk. There was substantial discussion around recognizing that there is always some element of risk to the environment, but that low risk could be manageable. Dr. Yarrow pointed out that risk is always going to be relative to what already exists. He suggested that CFIA could provide more examples – 10 to 15 – that would help proponents to evaluate environmental risk. Some participants suggested that these examples should include some on the data requirements for small crops.

Dr. Yarrow emphasized that CFIA’s job is not to be prescriptive; it is up to the developer to make the case as to whether or not a plant has a novel trait. But he also acknowledged that there needs to be a balance between providing sufficient clarity and at the same time providing flexibility for proponents in how they make their case. Some participants made the point that while a non-prescriptive approach is laudable, it does present challenges in terms of different interpretations among scientists and regulators.

On that topic, several questions were posed aimed at clarifying the requirements for notification and information:

- Are peer-reviewed papers always needed? Dr. Yarrow responded that peer-reviewed information is always

welcomed, but he acknowledged that in some cases the literature is not available and is not always required.

- What does “comparable Canadian environment” mean? Dr. Yarrow explained that a trial does not necessarily have to occur in Canada. The point is for the field trials to occur in an environment similar to the one in Canada where the plant is likely to be grown.
- Is risk assessment of environmental impact always done before the confined field trial? Dr. Yarrow explained that if the developer thinks there is risk to environmental safety or specific end use of the crop in question, he/she should do confined research field trials. But if the determination is made that there isn’t risk, then trials to assess environmental impact are not necessary.
- What constitutes “sound statistical analysis”? Dr. Yarrow indicated that CFIA will provide further guidance on this question, but it will not be prescriptive.
- What if an importer determines there is no novel trait in a particular plant, but a second importer determines that there is and the CFIA agrees with the second importer? Does that mean the first importer is also subject to regulatory oversight under Part V of the *Seeds Regulations*? Dr. Yarrow’s short answer was yes.
- Is the imposition of specific stewardship requirements designed to address specific environmental or health risks or business risks?
- Are events authorized for unconfined release exempt from subsequent application of Part V of the *Seeds Regulations*?
- There is a lack of detail on what “confined release” means. There needs to be flexibility to enable new crop introduction, that is, being able to grow the crop while building the data to move toward commercialization.
- With a non-prescriptive approach, there is potential for CFIA to be very busy with answering inquiries from proponents about assessing novelty, at least early on. Dr. Yarrow expressed the view that if the document is sufficiently clear, the opposite should be the case.

Again, resources for public plant breeders was raised as an issue, particularly for those crops that are relatively minor.

A decision tree appears on Page 7 of the draft directive that provides guidance on determining novelty. Some participants suggested that a decision tree that would indicate when each

Plants with Novel Traits

Working Group - Summary Report



October 27, 2008 - Ottawa, Ontario

section in the directive would be relevant to a particular proponent would also be helpful.

Presentation: Tanya Fielding, CFIA

Ms. Fielding outlined Section 4 of the draft Directive, which deals with notification and information requirements for environmental releases of plants other than PNTs. The categories of plants are:

- Plants developed to exhibit the same trait as a previously authorized PNT
- Plants resulting from intentional stacking of authorized traits through conventional breeding
- Products of rDNA technologies
- New crop species
- Authorized products commercialized by an entity other than the original applicant

Discussion

It was generally acknowledged that this section is a useful step forward.

The first area of discussion was around the impacts of Section 4 on trade. The point was made that the notification process must result in some official acknowledgement akin to an authorization in order to have some type of documentation for trade purposes. Are Sections 4.1, 4.2 and 4.5 consistent with the exemption provision of Part V, which states that previously approved products are exempt from notification? Asked how notifications will be publicly communicated, Dr. Yarrow responded that this information appears on the Biosafety Clearing House public web site.

Other areas where there needs to be more clarity:

- What constitutes “exhibiting the same trait”? Do Sections 4.1 and 4.3 apply even if the trait is the same but the protein expressed and genetic construct is different? The trait of glyphosate herbicide tolerance may be achieved using various mechanisms – are these all considered the same?
- The term “not subject to regulation” needs clarification. (i.e.: how can CFIA compel a proponent to submit notification?)

- When is a novel trait no longer considered novel?
- Clarify cases where the release of a plant that is not a PNT would require stewardship.
- The definition of “not previously cultivated” needs to be clarified.
- The definition of “identical construct” needs to be clarified.

Other comments:

- If the applicant owns the authorization, there should be a provision to de-authorize an original approval (i.e.: a company is changing its technology and does not want the product to continue to be used.)
- It may be useful to combine sections 4.1 and 4.3 because they prescribe the same measures.
- In Section 4.5, a request for evidence is required in the notification. Why is this request different than in other notifications?
- Nowhere in the regulations is there the basis for re-regulating an approved event.

Dr. Yarrow suggested that addressing the concerns and questions in the next draft of Section 4 will take time and CFIA does not want to hold back the rest of the process; they want to achieve their 2009 targets. Therefore, Section 4 may be dealt with separately while the rest of the process continues to move forward on track.

Presentation: Tanya Fielding, CFIA

Section 5 of the draft Directive deals with authorizations for environmental release of PNTs and other plants regulated under Part V of the *Seeds Regulations*. Main points in this section are:

- PNTs and other regulated plants may not be released into the environment without explicit authorization from the PBO following notification
- New information becoming available after a plant has been released into the environment is required to be submitted by the proponent to the PBO
- Certain stewardship requirements may be removed from an unconfined environmental release where a proponent has made the business decision to remove an authorized PNT from the marketplace.

Discussion

An important area of discussion was around the responsibility of the original PNT holder to monitor farm saved seed that has been removed from the marketplace by the original owner. Several questions about stewardship and liability were raised: How will the requirements for farm saved seed be enforced after the removal of the PNT from the marketplace? How long will a developer have responsibility for farm saved seed? Who owns an authorization if the original applicant gives notice of discontinuation? Why is the original applicant responsible for communicating new information on a discontinued product? It was suggested that this policy needs to be coordinated with the food and feed sectors. CFIA took note of these questions and comments.

Other comments:

- There needs to be clarity on the motive of CFIA for the section on “de-authorization”.
- Is the term “relevant new information” intended to broaden the information or does it relate back to information relevant to the safety assessment?
- From a financial standpoint, who is responsible for seed and seeded areas when new information comes forward that impacts public health and safety after a PNT already has been approved?

Focus on Related Issues/Questions

Discussion

The last portion of the meeting was focused on two questions: Having reviewed the draft Directive, what additional questions need to be addressed, and what are the related issues/opportunities?

There was a general sense in the room that CFIA is moving in the right direction with the draft Directive but that there is still much work ahead.

One of the main areas of progress at the meeting was the recognition that there is no such thing as zero risk with respect to environmental risk, and that more examples need to be developed as part of the draft Directive to demonstrate low or relative risk. Dr. Yarrow noted that the Organization for

Economic Co-operation and Development has a working group on harmonizing biotech regulations; there are ongoing discussions about the challenges of trying to establish risk baselines. He suggested that 10 to 15 more examples in the draft Directive may be the best way of providing breeders and proponents with more guidance. He cautioned that examples should be used as guidance, not in a prescriptive manner.

Funding was a key area of discussion. Several participants said that additional funding and an outreach program are needed to equip public breeders with a broader understanding of the regulatory process, and the steps necessary to put together packages for regulatory processing.

Next Steps

1. This meeting was CFIA's first step on gathering feedback in its draft Directive.
2. A small, focused group from the public breeding community will be assembled between now and the end of the year to address issues in Chapter 2 and appendix 1B, and to develop examples.
3. The CFIA was asked to develop an accompanying document that shows how each suggestion from this meeting was addressed in the next revised draft Directive.
4. The CFIA will consider removing Chapter 4 from the draft Directive, to be dealt with separately.
5. The next step in consultations will be to circulate the revised draft Directive via email to a broad group of stakeholders for comment. All participants at this meeting will be included.
6. By early 2009, the Directive will have been revised to reflect input from the email consultation.

Wrap-up

In conclusion, Dr. Yarrow described the meeting as a “rich conversation” that was very helpful in providing feedback.